NORTH DAKOTA
DEPARTMENT *of* HEALTH

Health Alert Network

OCT. 29, 2009

HEALTH ADVISORY

Emergency Use Authorization Issued for Peramivir

The U.S. Food and Drug Administration (FDA) issued an emergency use authorization (EUA) on Friday, Oct. 23, 2009, for the use of the investigational antiviral drug Peramivir intravenous (IV) in certain adult and pediatric patients with confirmed or suspected 2009 H1N1 influenza infection who are admitted to a hospital.

Specifically, Peramivir IV is only authorized for hospitalized adult and pediatric patients for whom therapy with an IV drug is clinically appropriate, based on one or more of the following reasons:

1. The patient is not responding to either oral or inhaled antiviral therapy.

2. When drug delivery by a route other than an intravenous route -- e.g., enteral (absorbed by the intestines) or inhaled -- is not expected to be dependable or feasible.

3. When the clinician judges IV therapy is appropriate due to other circumstances (for adults only).

There are no FDA-approved intravenously administered antiviral drugs for the treatment of influenza. Peramivir is the only intravenously administered influenza treatment currently authorized for use under EUA for 2009 H1N1 infections.

Clinicians considering use of Peramivir IV under EUA must read and understand the content of the FDA-issued Emergency Use Authorization of Peramivir IV: Fact Sheet For Health-Care Providers (www.cdc.gov/h1n1flu/eua) prior to initiating a request and must agree to comply with terms and conditions of authorized use of Peramivir per the FDA-issued EUA. Clinicians who, after reading the Fact Sheet for Health-Care Providers, wish to obtain Peramivir IV for a patient can download the request form (or access an electronic request portal) at www.cdc.gov/H1N1flu/EUA/peramivir_recommendations.htm.

Additionally, clinical studies of Peramivir IV in hospitalized patients are currently underway. Clinicians who wish to consider whether their patients would be appropriate for inclusion in those studies should refer to www.ClinicalTrials.gov for more information about these trials.

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Clinicians and public health officials are reminded that two other neuraminidase inhibitor drugs i.e., oseltamivir (Tamiflu®) and Zanamivir (Relanza®) are available, and their use may be appropriate in some patients with 2009 H1N1 influenza infections. Conditions for use of these agents and additional guidance are available at www.cdc.gov/H1N1flu/recommendations.htm and www.cdc.gov/h1n1flu/eua/.

Additional information on 2009 Influenza H1N1 diagnosis and patient management is available at http://emergency.cdc.gov/h1n1antivirals or by calling 1.800.CDC.INFO (1.800.232.4636), 24 hours a day, 7 days a week. Updates are placed on the website and made available to callers whenever new information becomes available. We encourage you to check the website regularly.

Categories of Health Alert messages:

- *Health Alert conveys the highest level of importance; warrants immediate action or attention.*
- *Health Advisory provides important information for a specific incident or situation; may not require immediate action.*
- *Health Update provides updated information regarding an incident or situation; no immediate action necessary.*
- *Health Information provides general information that is not necessarily considered to be of an emergent nature.*

This message is being sent to local public health units, clinics, hospitals, physicians, tribal health, North Dakota Nurses Association, North Dakota Long Term Care Association, North Dakota Healthcare Association, North Dakota Medical Association, and hospital public information officers.